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No. 98-245

In The

Supreme Court of the United States

OCTOBER TERM, 1998

HOWMEDICA, INC., A DIVISION OF
PFIZER HOSPITAL PRODUCTS GROUP, INC.,

Petitioner,

v.

GEORGE E. ELBERT,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF THE PETITION FOR WRIT OF CERTIORARI

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September 8, 1998

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The Pharmaceutical Research and Manufacturers of America (PhRMA) hereby seeks leave pursuant to this Court's Rule 37.2 to file the attached brief *amicus curiae* in support of Petitioner Howmedica, Inc. Petitioner has consented to the filing of this brief. Respondent's counsel has not responded to repeated requests for consent, but an assistant to

Respondent's counsel has stated orally that Respondent does not consent to the filing of this brief.[1]

PhRMA is a voluntary, nonprofit association representing the country's leading research-based pharmaceutical and biotechnology companies. PhRMA's member companies invest nearly $ 21 billion annually in discovering and developing new medicines, and are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives.

PhRMA frequently participates as *amicus curiae* in judicial proceedings involving issues of concern to the pharmaceutical industry. PhRMA takes particular interest in cases that concern the standards for admitting scientific testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and submitted briefs *amicus curiae* in both *Daubert*[2] and in *General Electric Co. v. Joiner*, 118 S.Ct. 512 (1997) (holding that trial courts' evidentiary determinations under *Daubert* should be accorded significant deference).

The instant case presents the questions whether expert scientific testimony determined to be inadmissible after trial must be considered by the trial court in reviewing a motion made under Fed. R. Civ. P. 50(b), and whether the trial court must always conduct a new trial under such circumstances, even if no competent scientific evidence supporting an essential element of a plaintiff's claim remains for a jury to consider. Since the product liability claims that are brought against pharmaceutical companies typically require expert

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[1] Petitioner's letter of consent has been filed with the Clerk of the Court.

[2] The brief was submitted by PhRMA's predecessor, the Pharmaceutical Manufacturers Association.

scientific testimony, the pharmaceutical industry has a substantial interest in ensuring the proper application of *Daubert*. If evidence not meeting *Daubert*'s requirements is incorrectly admitted at trial, it is important to the pharmaceutical industry that the trial court not be required to consider the evidence under Rule 50(b), and that the trial court have discretion to resolve the case in a just and efficient manner.

PhRMA believes that its participation as *amicus curiae* will provide the Court with a broader perspective on the importance to the pharmaceutical industry of protecting the trial court's post-trial discretion under *Daubert*. Accordingly, PhRMA respectfully seeks the Court's leave to file the attached brief supporting Petitioner.

Respectfully submitted,

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The Pharmaceutical Research and Manufacturers of America (PhRMA) submits this brief *amicus curiae* in support of the petition for a writ of certiorari filed by Howmedica, Inc.[1]

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[1] Pursuant to Supreme Court Rule 37.6, PhRMA hereby states that no counsel for a party has authored this brief in whole or in part, and that no person or entity other than PhRMA or its members has made a monetary contribution to the preparation or submission of this brief. Petitioner Howmedica, Inc., is a subsidiary of Pfizer Inc., which is a PhRMA member.

INTEREST OF THE *AMICUS CURIAE*

PhRMA is a voluntary, nonprofit association representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA's member companies invest nearly $21 billion annually in discovering and developing new medicines. These companies are the source of nearly all new drugs that are discovered and marketed throughout the world.

The pharmaceutical industry is based on science, from the discovery of promising new chemical entities through their testing, development, and distribution. Science also must play a central role in product liability cases alleging injury from these products. Conveying scientific information to a jury under these circumstances necessarily requires expert testimony. Unless unqualified experts and unreliable scientific theories are excluded, juries in these complex cases may award damages that are not founded on reliable scientific information. Similarly, unless cases determined post-trial to lack relevant and reliable evidence to support a plaintiff's position are resolved expeditiously, courts and pharmaceutical companies will be required to expend their limited resources on unnecessary and unwarranted litigation.

The Ninth Circuit's requirements that excluded evidence be considered under Rule 50(b) and that post-trial exclusion of expert testimony be followed by a new trial undermine the trial court's discretion to conclude cases expeditiously when they are not based on *relevant* and *reliable* scientific testimony. Because pharmaceutical litigation invariably requires trial courts to review expert scientific testimony, and because the cost of defending against meritless lawsuits deters innovation and the availability of medications, PhRMA is filing this brief in support of the petition for a writ of certiorari.

INTRODUCTION AND SUMMARY

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), this Court held that Fed. R. Evid. 702 "assign[s] to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." 509 U.S. at 597. *Daubert* directs the trial court to grant summary judgment or judgment as a matter of law if it determines that the evidence is insufficient to support a verdict for the plaintiff. *Id.* at 596. *General Electric Co. v. Joiner*, 118 S.Ct. 512 (1997), which followed *Daubert*, underscores the importance of protecting the trial court's discretion to make determinations concerning the admissibility of scientific testimony. *Daubert* and *Joiner* confirm that the trial court has both the authority and the responsibility to ensure that scientific disputes are resolved based solely on relevant and reliable scientific testimony.

Adherence to the principles recognized in *Daubert* and *Joiner* is equally important at the post-trial stage of litigation. If the trial or appellate court determines that scientific evidence was improperly admitted under Fed. R. Evid. 702, and that a jury's verdict therefore was based on unreliable expert testimony, the error should be corrected fairly and expeditiously. Accordingly, the trial court should not be required to consider unreliable and inadmissible testimony under Fed. R. Civ. P. 50(b). Nor should the trial court be required to conduct a new trial. Instead, the trial court should have the option of entering judgment as a matter of law under Rule 50(b) if it determines, in its proper exercise of discretion, that a plaintiff can produce no competent scientific evidence to support an essential element of the plaintiff's claim.

Protecting the trial court's discretion under *Daubert* is particularly important to the pharmaceutical industry. Pharmaceutical manufacturers face product liability claims that

typically require expert testimony on complex scientific issues. Although it is obviously preferable for the trial court to rule that unreliable evidence is inadmissible prior to trial, in some cases trial courts may reconsider *Daubert* rulings after trial, and in others the trial court's ruling may be reversed on appeal. Requiring a new trial in every instance — even when the admissible scientific evidence cannot support a verdict for the plaintiff — unnecessarily subjects defendants, including pharmaceutical manufacturers, to additional burdensome and costly litigation.

For this reason, PhRMA urges this Court to grant the petition in this case, reverse the Ninth Circuit's decision, and adopt the flexible approach articulated by the Third Circuit in *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153 (3d Cir. 1993), which accords discretion to the trial court to determine the appropriate course following a post-trial determination that evidence was improperly admitted during trial.

REASONS FOR GRANTING THE PETITION

I. THE NINTH CIRCUIT'S INTERPRETATION OF RULE 50(b) CONFLICTS WITH DECISIONS OF THE THIRD CIRCUIT AND UNDERMINES THIS COURT'S DECISION IN *DAUBERT*.

A. The Ninth Circuit's Decision Misinterprets Rule 50(b) And Conflicts With Decisions of the Third Circuit.

The Ninth Circuit's determination that Fed. R. Civ. P. 50(b) requires consideration of evidence that was improperly admitted during trial rests on a misunderstanding of that rule. Rule 50 is a "judicial control device[]" adopted to permit trial courts to remove from the jury's consideration "cases or issues when the facts are sufficiently clear that the law requires a particular result." 9A Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 2521, at

240 (2d ed. 1994). The purpose of the rule is "to speed litigation and avoid unnecessary retrials." *Neely v. Eby Construction Co.*, 386 U.S. 317, 326 (1967). *See also Montgomery Ward & Co. v. Duncan*, 311 U.S. 243, 250 (1940). In accordance with that purpose, this Court held in *Neely* that an appellate court may direct entry of a judgment when it determines that the evidence was insufficient to support the jury's verdict.

Rule 50 requires entry of judgment as a matter of law if "there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." Fed. R. Civ. P. 50(a)(1). "The question is not whether there is literally no evidence supporting the party against whom the motion is directed but whether there is evidence upon which the jury *properly* could find a verdict for that party." Wright & Miller § 2524, at 253-254 (emphasis added). The standard is the same whether the Rule 50 motion is made before or after the case is submitted to the jury. *Id.* § 2537, at 347.

Evidence that fails to meet the requirements of Fed. R. Evid. 702 is not admissible. Such evidence is therefore not "legally sufficient" within the meaning of Rule 50, and a jury's verdict in reliance on such evidence is not proper. Requiring courts to consider such evidence under Rule 50(b) does not speed litigation or avoid unnecessary trials, but instead does precisely the opposite, contrary to the purposes of Rule 50. *See also* Fed. R. Civ. P. 1 (Federal Rules of Civil Procedure "shall be construed . . . to secure the just, speedy, and inexpensive determination of every action.").

There is a conflict among the circuits on this important issue. The Third Circuit has held that it is inappropriate to consider excluded testimony under Rule 50(b), and has upheld the trial court's discretion to determine, based on a record containing only admissible evidence, the fair and expeditious remedy for the improper admission of evidence at trial.

Lightning Lube, Inc. v. Witco Corp., 4 F.3d 1153; *Aloe Coal Co. v. Clark Equipment Co.*, 816 F.2d 110, 115 (3rd Cir. 1987), *cert. denied*, 484 U.S. 853 (1987). The Third Circuit recognized that other courts of appeals have held to the contrary, but correctly noted the absence of any "reasoned elaboration to support [the] thesis that '[i]n ruling on the sufficiency of evidence the trial court must take the record as presented to the jury and cannot enter judgment on a record altered by the elimination of incompetent evidence.'" *Aloe Coal Co. v. Clark Equipment Co.*, 816 F.2d at 115 (internal citation omitted).[2]

B. The Ninth Circuit's Decision Undermines the Principles of *Daubert*.

The Ninth Circuit's conclusion that Rule 50(b) requires consideration of inadmissible expert testimony is contrary to this Court's decision in *Daubert*. *Daubert* held that Fed. R. Evid. 702 requires trial judges to perform the role of "gatekeeper," screening scientific testimony to ensure that it is relevant and reliable. 509 U.S. 589, 597.[3] This gatekeeping function entails both a determination that a

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[2] Other courts of appeals have taken the same position as the Ninth Circuit. *See Jackson v. Pleasant Grove Health Care Ctr.*, 980 F.2d 692 (11th Cir. 1993); *Douglass v. Eaton Corp.*, 956 F.2d 1339 (6th Cir. 1992); *Sumitomo Bank v. Product Promotions, Inc.*, 717 F.2d 215 (5th Cir. 1983); *Midcontinent Broadcasting Co. v. North Cent. Airlines, Inc.*, 471 F.2d 357 (8th Cir. 1973).

[3] Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Fed. R. Evid. 702.

witness has the requisite qualifications to testify to the matters at issue and that the opinion being asserted is scientifically reliable. If either of these components is lacking, the evidence must be excluded.

In *Daubert*, this Court emphasized the duty of the trial court to grant summary judgment or judgment as a matter of law if the evidence presented is too insubstantial to support a verdict in favor of plaintiff. 509 U.S. at 596.

Daubert directs trial courts to exercise their discretion to grant judgment as a matter of law — under either Rule 50 or Rule 56[4] — "in the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true." 509 U.S. at 596. That admonition has been followed by several federal circuit and district courts.[5] Despite *Daubert*, the Ninth Circuit held in

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[4] Rule 56 directs the trial court to grant summary judgment if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56. The standard for granting summary judgment "mirrors" the standard applied under Rule 50: "[T]he inquiry under each is the same: whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-252 (1986).

[5] *See, e.g., Conde v. Velsicol Chemical Corp.*, 24 F.3d 809 (6th Cir. 1994) (holding that, where expert testimony is insufficient to permit a reasonable juror to conclude that the position taken is more likely than not true, a verdict may be directed or summary judgment granted even over expert testimony in evidence); *See also* G. Michael Fenner, *The Daubert Handbook: The Case, Its Essential Dilemma, and Its Progeny*, 29 Creighton L. Rev. 939, 1084-1085 (1996) (listing all cases in which federal courts have granted summary judgment or directed a verdict in accordance with the Supreme Court's holding in *Daubert*).

this case that the magistrate judge "erred in excluding the erroneously admitted evidence when deciding Howmedica's Rule 50(b) motion after remand." *Elbert v. Howmedica, Inc.*, 143 F.3d 1208, 1209 (9th Cir. 1998); Pet. App. 3. The Ninth Circuit's direction to the trial court to consider inadmissible scientific testimony is inconsistent with *Daubert's* mandate to the trial court to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable," 509 U.S. at 589, and to end litigation based on scientifically invalid evidence at its earliest stage.[6]

The Ninth Circuit's decision in this case relies on *Schudel v. General Electric Co.*, 120 F.3d 991 (9th Cir. 1997), *cert. denied*, 118 S.Ct. 1560 (1998), a decision that further illustrates the tension between the Ninth Circuit's position and *Daubert*.[7] In *Schudel*, the trial court improperly permitted the jury to consider an unproven scientific theory. After the jury in *Schudel* returned a verdict in favor of plaintiff, the trial

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[6] Indeed, the Ninth Circuit itself initially followed this Court's direction when considering the *Daubert* case on remand. Rather than remanding the case to the district court, the Ninth Circuit concluded that "the interests of justice and judicial economy" favored the appellate court's analysis under the new *Daubert* standard of the evidence previously submitted in the trial court. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995), *cert. denied*, 516 U.S. 869 (1995). The Court determined that the evidence could not have satisfied the new standard and would thus have been inadmissible under Fed. R. Evid. 702. *Id.* at 1322. Accordingly, the Ninth Circuit affirmed the district court's prior grant of summary judgment for defendant. *Id.* The Ninth Circuit's decision on remand in *Daubert* was sensible, and it makes even more sense to give the trial court, which observed the first trial and is familiar with the issues and the parties, discretion to decide whether a *Daubert* error warrants a new trial.

[7] The petition for a writ of certiorari in *Schudel* was filed by the plaintiffs, and did not present the question presented by the petition in this case.

court held that the testimony should have been excluded under *Daubert*. The trial court found the remaining evidence insufficient to support the jury verdict and therefore granted judgment for defendant under Rule 50(b). On appeal, the Ninth Circuit agreed that the evidence should have been excluded under *Daubert* but nevertheless held that the trial court had erred in failing to consider that evidence in its Rule 50(b) determination.

II. PHARMACEUTICAL PRODUCT LIABILITY CASES ILLUSTRATE THE IMPORTANCE OF GRANTING COURTS APPROPRIATE POST-TRIAL DISCRETION TO APPLY THE PRINCIPLES OF *DAUBERT*.

Product liability claims brought against pharmaceutical companies typically rely on scientific testimony. The pharmaceutical industry therefore has a substantial interest in ensuring that only relevant and reliable scientific testimony is admitted at trial. If scientific testimony that is not relevant or reliable is incorrectly admitted at trial, it is also important to ensure that the post-trial proceedings permit an efficient and just resolution of the case. The Ninth Circuit's decision in the instant case undermines these interests.

A. Requiring a New Trial Where The Scientific Evidence Does Not Support a Plaintiff's Case Is Wasteful of the Courts' and the Defendants' Resources.

The Ninth Circuit's decision requires trial courts and litigants to engage in an exercise in legal and factual futility. Although there may be situations in which a plaintiff would have been able to substitute a qualified expert to replace the disqualified expert if the trial court's initial evidentiary ruling had been correct, these situations are likely to be few and far between. As the Third Circuit pointed out, there is "no reason to suppose that a litigant would hold back significant

evidence at trial." *Lightning Lube*, 4 F.3d at 1199. The instant case bears this out: on remand, Respondent did not seek to substitute a qualified expert on the issues of negligence and breach of warranty.

The Third Circuit's observation is true of most other pharmaceutical cases as well, which typically turn on an expert's scientific theory of causation. Once a plaintiff's theory has been held to be inadmissible under *Daubert*, it is highly unlikely that plaintiff will be able to offer a new, admissible theory with which to prove causation.[8] Notwithstanding this predictable result, the Ninth Circuit's ruling requires that a second trial take place.[9] Such a futile exercise wastes judicial resources and subjects the pharmaceutical industry — which already faces substantial litigation burdens[10] — to the additional cost and burden of

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[8] As the Ninth Circuit noted in *Daubert*:

> [T]o augment the substantive testimony as to causation [on remand to the trial court] would require the experts to change their conclusions altogether. Any such tailoring of the experts' conclusions would, at this stage of the proceedings, fatally undermine any attempt to show that these findings were "derived by the scientific method." Plaintiffs' experts must, therefore, stand by the conclusions they originally proffered . . . .

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1322.

[9] Even under the Ninth Circuit's ruling, if it is clear after further development of the facts and witnesses that the plaintiff cannot present scientific evidence that is sufficient to support a favorable verdict under *Daubert*, the trial court should be permitted to enter summary judgment in favor of the defendant.

[10] *See* W. Kip Viscusi, Michael J. Moore, & James Albright, *The Effect of Products Liability Litigation on Innovation: A Statistical Profile of Pharmaceutical Industry Liability, 1976-1989*, 24 Seton Hall L. Rev. 1418, 1434 (1994) ("The pharmaceutical industry, which is one of the most

defending against a claim that the trial court has previously determined to be unsupported by competent scientific evidence. The expenses entailed in defending against meritless claims ultimately deter research and innovation.[11]

B. Requiring Consideration of Evidence That Is Not Relevant and Reliable Undermines *Daubert*.

The Ninth Circuit's interpretation of Rule 50(b) requires judicial consideration of evidence that has been held to be inadmissible under Rule 702 and *Daubert*. Because of the significance of the *Daubert* decision in the context of pharmaceutical litigation, the Ninth Circuit's ruling is of particular concern to the industry.

Pharmaceutical litigation often involves consideration of complex scientific testimony. As Marcia Angell, M.D., the

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innovative industries in the economy, has been particularly hard hit by the surge in liability costs.").

[11] *See* Steven Garber, The Institute for Civil Justice, *Product Liability and the Economics of Pharmaceuticals and Medical Devices* 142 (1993) ("Effects on innovative effort may be the most important element of the effects of liability on the economic performance of these industries."); Richard J. Mahoney & Stephen E. Littlejohn, *Innovation on Trial: Punitive Damages Versus New Products*, 246 Science 1395, 1397 (Dec. 15, 1989) ("The result of this liability expansion has been a slowing of innovation in entire fields of inquiry, especially in those having to do with health care."). *See also* American Medical Association, *Report of the Board of Trustees: Impact of Product Liability on the Development of New Medical Technologies* 1 (1988), finding that:

> Innovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance. Certain older technologies have been removed from the market, not because of sound scientific evidence indicating lack of safety or efficacy, but because product liability suits have exposed manufacturers to unacceptable financial risks.

Executive Editor of the New England Journal of Medicine, has noted, such testimony is particularly difficult for juries to evaluate, since they usually have no special expertise in the area.[12] Compounding this inherent difficulty, the tort system encourages lawyers under contingency fee arrangements to bring meritless suits, impose burdensome defense costs on defendants, and seek to collect quick settlements.[13] As a result "scientific testimony in the courtroom is often at most only marginally related to scientific evidence. . . . [causing] a growing gap between scientific reality and what passes for it in the courtroom."[14]

As Dr. Angell noted, "[t]he *Daubert* decision was a brave step toward remedying the situation,"[15] because it grants the trial court the authority to exclude from the jury's consideration scientific testimony that is not relevant and reliable, thereby preventing the jury from being swayed by emotional appeals premised on "junk science."

Where the trial court errs and admits testimony that should have been excluded under *Daubert*, this evidence should not be given weight in the context of a Rule 50(b) motion. Instead, once a determination has been made that the evidence was admitted in error, the trial court should be able to exclude the evidence from further consideration. If the excluded evidence was the only evidence relied on by the plaintiff regarding an essential element of its claim, and certainly if the plaintiff cannot show that it was harmed by the district court's erroneous ruling, the trial court should be able

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[12] Marcia Angell, *Science on Trial* 204 (1996).

[13] *Id.* at 203.

[14] *Id.* at 132.

[15] *Id.*

to end the case by granting judgment as a matter of law in favor of the defendant.

The trial court's ability to exclude evidence that does not meet *Daubert* standards from consideration under Rule 50(b) safeguards this Court's holding in *Daubert* and minimizes the costs of baseless litigation by permitting courts to grant judgment as a matter of law and conclude litigation where insufficient scientific evidence exists to warrant a second trial.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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